

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Howard Bernstein, Yan Zhang, M. Amin Khan and Mark A. Tracy
Application No.: 10/797,718 Group Art Unit: 1615
Filed: March 10, 2004 Examiner: Not Assigned
Confirmation No.: 4117
Title: MODULATED RELEASE FROM BIOCOMPATIBLE POLYMERS

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
7/27/04	Christina M. Sweeney
Date	Signature
Christina M. Sweeney	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

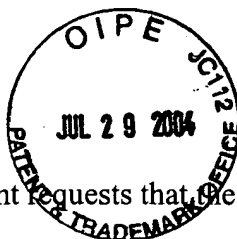
Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application Nos. 09/274,613, 09/056,566, 08/237,057 and 08/727,531, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.



☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira

Susan M. Abelleira

Registration No.: 42,252

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: July 27, 2004

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 26, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1003-012		APPLICATION NO. 10/797,718	
	FIRST NAMED INVENTOR Howard Bernstein		FILING DATE March 10, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 4117	GROUP 1615

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,675,189	06/23/87	Kent, J.S. <i>et al.</i>
	AB	4,962,091	10/09/90	Eppstein, D.A. <i>et al.</i>
	AC	3,523,906	08/11/70	Vrancken, M.N. <i>et al.</i>
	AD	3,691,090	09/12/72	Kitajima, M. <i>et al.</i>
	AE	3,737,337	06/05/73	Schnoring, H. <i>et al.</i>
	AF	3,887,699	06/03/75	Yolles, S.
	AG	4,389,330	06/21/83	Tice, T.R. <i>et al.</i>
	AH	4,530,840	07/23/85	Tice, T.R. <i>et al.</i>
	AI	4,542,025	09/17/85	Tice, T.R. <i>et al.</i>
	AJ	4,835,139	05/30/89	Tice, T.R. <i>et al.</i>
	AK	4,891,225	01/02/90	Langer, R.S. <i>et al.</i>
	AA2	3,891,570	06/24/75	Fukushima, M. <i>et al.</i>
	AB2	4,391,797	07/05/83	Folkman, M.J. <i>et al.</i>
	AC2	5,176,907	01/05/93	Leong, K.W.
	AD2	5,122,367	06/16/92	Ron, E. <i>et al.</i>
	AE2	5,145,674	09/08/92	Lane, G.A. <i>et al.</i>
	AF2	4,711,782	12/08/87	Okada, H. <i>et al.</i>
	AG2	5,126,147	06/30/92	Silvestri, L.J. <i>et al.</i>
	AH2	5,192,741	03/09/93	Orsolini, P. <i>et al.</i>
	AI2	4,732,889	03/22/88	Cynshi, O. <i>et al.</i>
	AJ2	4,879,272	11/07/89	Shimoda, N. <i>et al.</i>
	AK2	4,992,419	02/12/91	Woog, H. <i>et al.</i>
	AA3	4,853,218	08/01/89	Yim, Z. <i>et al.</i>
	AB3	4,235,236	11/25/80	Theeuwes, F.
	AC3	4,906,474	03/06/90	Langer, R.S. <i>et al.</i>
	AD3	5,019,400	5/28/91	Gombotz, W.R. <i>et al.</i>

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 26, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1003-012		APPLICATION NO. 10/797,718	
	FIRST NAMED INVENTOR Howard Bernstein		FILING DATE March 10, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 4117	GROUP 1615

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	4,981,696	1/1/91	Loomis, G.L. <i>et al.</i>
	AF3	4,637,905	1/20/87	Gardner, D.L.
	AG3	4,897,268	1/30/90	Tice, T.R. <i>et al.</i>
	AH3	4,767,628	8/30/88	Hutchinson, F.G.
	AI3	3,928,566	12/23/75	Briggs, A.R. <i>et al.</i>
	AJ3	4,166,800	9/4/79	Fong, J.W.
	AK3	4,530,901	7/13/85	Weissmann, C.
	AA4	4,871,538	10/02/89	Yim, Z. <i>et al.</i>
	AB4	B1 4,985,404	04/21/92	Mitchell, J.W.
	AC4	4,655,777	04/07/87	Dunn, R.L., <i>et al.</i>
	AD4	5,075,115	12/24/91	Brine, C.J.
	AE4	5,344,654	09/06/94	Rueger, D.C., <i>et al.</i>
	AF4	4,237,114	12/02/80	Cardarelli, N.F.
	AG4	4,806,524	02/21/89	Kawaguchi, T., <i>et al.</i>
	AH4	4,252,791	02/24/81	Grossberg, S.E., <i>et al.</i>
	AI4	5,441,734	08/15/95	Reichert, P., <i>et al.</i>
	AJ4	5,413,797	05/09/95	Khan, M.A., <i>et al.</i>
	AK4	5,656,297	08/12/97	Bernstein, <i>et al.</i>
	AA5	5,912,015	06/15/99	Bernstein, <i>et al.</i>

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 26, 2004 / (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1003-012		APPLICATION NO. 10/797,718	
	FIRST NAMED INVENTOR Howard Bernstein		FILING DATE March 10, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 4117	GROUP 1615

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	WO91/12882	05/09/91	Medgenix Group S.A.		
	AM	WO96/07399A1	14/03/96	Takeda Chemical Industries, LTD		
	AN	WO93/07861	29/04/93	Board of Regents, The University of Texan System		
	AO	WO93/25221	23/12/93	Alkermes Controlled Therapeutics, Inc.		
	AP	WO90/09166	23/08/90	Biosearch, Inc.		
	AQ	WO90/13780	15/11/90	Enzytech, Inc.		
	AL2	WO92/11844	23/7/92	Enzytech, Inc.		
	AM2	WO95/29664 A1	09/11/95	Alkermes Controlled Therapeutics, Inc.		
	AN2	WO94/12158	09/06/94	Alkermes Controlled Therapeutics, Inc.		
	AO2	0633 020 A1	11/01/95	Takeda Chemical Industries, Inc.		
	AP2	WO93/17668	16/09/93	Alkermes Controlled Therapeutics, Inc.		
	AQ2	WO94/07469	04/14/94	Dynagen, Inc.		
	AL3	0580 428 A1	01/26/94	Takeda Chemical Industries, Inc.		
	AM3	0537559 A1	21/04/93	Atrix Laboratories, Inc.		
	AN3	0266119 A3	04/05/88	Souther Research Institute & The UAB Research Foundation		
	AO3	0330180 A1	30/08/89	Biomaterials Universe, Inc.		
	AP3	WO89/03678	05/05/89	Stolle Research & Development Corporation		
	AQ3	WO90/13285	15/11/90	Enzytech, Inc.		
	AL4	0 595 030 A2	05/09/91	Tanabe Seiyaku, Co., LTD.		
	AM4	WO93/02712	18/02/93	Danbiosyst UK Limited		
	AN4	WO95/11010	27/04/95	Genetech, Inc.		
	AO4	WO94/19373 A1	01/09/94	Schering Corporation		

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
1733.1003-012

APPLICATION NO.
10/797,718

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

July 26, 2004

(Use several sheets if necessary)

FIRST NAMED INVENTOR
Howard Bernstein

FILING DATE
March 10, 2004

EXAMINER
Not Assigned

CONFIRMATION NO.
4117

GROUP
1615

FOREIGN PATENT DOCUMENTS

[illegible]

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 26, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1003-012		APPLICATION NO. 10/797,718	
	FIRST NAMED INVENTOR Howard Bernstein		FILING DATE March 10, 2004	
	EXAMINER Not Assigned	CONFIRMATION NO. 4117	GROUP 1615	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Pratt, L., <i>et al.</i> , "The Effect of Ionic Electrolytes on Hydrolytic Degradation of Biodegradable Polymers: Mechanical and Thermodynamic Properties and Molecular Modeling," <i>J. Polymer Science</i> 31(7):1759-1769 (1993).	
AS	Costantino, H. R., <i>et al.</i> , "Solid-Phase Aggregation of Proteins under Pharmaceutically Relevant Conditions," <i>J. of Pharmaceutical Sciences</i> , 83(12):1662-1669 (1994).	
AT	Costantino, H. R., <i>et al.</i> , "Moisture-Induced Aggregation of Lyophilized Insulin," <i>Pharmaceutical Research</i> , 11(1):21-29 (1994).	
AU	Costantino, H.R., <i>et al.</i> , "Aggregation of a Lyophilized Pharmaceutical Protein, Recombinant Human Albumin: Effect of Moisture and Stabilization by Excipients," <i>Biotechnology</i> , 13:493-496 (1995).	
AV	Creighton, T.E., "Physical Forces That Determine the Properties of Proteins," <i>In Proteins, Structures and Molecular Principles</i> , (NY: W.H. Freeman and Company), pp. 149-150.	
AW	Cunningham, B. C., <i>et al.</i> , "Dimerization of Human Growth Hormone by Zinc," <i>Science</i> , 253:545-548 (August 1991).	
AX	Sato, Toyomi, <i>et al.</i> , "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," <i>Pharmaceutical Research</i> , 5(1):21-29 (1988).	
AY	Langer, R., "New Methods of Drug Delivery," <i>Science</i> , 249:1527-1533 (September 1990).	
AZ	Liu, W. R., <i>et al.</i> , "Moisture-Induced Aggregation of Lyophilized Proteins in the Solid State," <i>Biotechnology and Bioengineering</i> , 37:177-184 (1991).	
AR2	Lu, W., and Park, T. G., "Protein Release from Poly(lactic-co-glycolic acid) Microspheres: Protein Stability Problems," <i>PDA J. of Pharmaceutical Science & Technology</i> , 49(1):13-19 (Jan-Feb 1995).	
AS2	Cohen, S., <i>et al.</i> , "Controlled Delivery Systems for Proteins Based on Poly(Lactic/Glycolic Acid) Microspheres," <i>Pharmaceutical Research</i> , 8(6):713-720 (1991).	
AT2	Hora, M.S. <i>et al.</i> , "Release of Human Serum Albumin from Poly(lactide-co-glycolide) Microspheres," <i>Pharmaceutical Research</i> , 7(11):1190-1194 (1990).	

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 26, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1003-012		APPLICATION NO. 10/797,718	
	FIRST NAMED INVENTOR Howard Bernstein		FILING DATE March 10, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 4117	GROUP 1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AU2	Hageman, M.J., <i>et al.</i> , "Preformulation Studies Oriented Toward Sustained Delivery of Recombinant Somatotropins," <i>J. Agric. Food Chem.</i> , 40:348-355 (1992).
AV2	Cleland, J. L., <i>et al.</i> , "Characterization of Recombinant Human Growth Hormone-PLGA Formulations in Animals," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 22:143-144 (1995).
AW2	Cleland, J. L., <i>et al.</i> , "One Month Continuous Release Recombinant Human Growth Hormone-PLGA Formulations," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 22:149-150 (1995).
AX2	Mullerad, J., <i>et al.</i> , "Delivery of IL-1 Microspheres to Tumor Macrophages," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 22:512-513 (1995).
AY2	Cleland, J. L., <i>et al.</i> , "In Vitro Release of Bioactive Recombinant Human Interferon- γ From PLGA Microspheres," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 22:518-519 (1995).
AZ2	Park, T. G., <i>et al.</i> , "Importance of <i>In Vitro</i> Experimental Conditions on Protein Release Kinetics, Stability and Polymer Degradation in Protein Encapsulated Poly(D,L-Lactic Acid-Co-Glycolic Acid) Microspheres," <i>J. of Controlled Release</i> , 33:211-222 (1995).
AR3	Nagata, S., <i>et al.</i> , "Synthesis in <i>E. Coli</i> of a Polypeptide with Human Leukocyte Interferon Activity," <i>Nature</i> , 284:316-320 (March 1980).
AS3	Rubinstein, M., "The Structure of Human Interferons," <i>Biochimica et Biophysica Acta.</i> , 695:5-16 (1982).
AT3	Sah, H., <i>et al.</i> , "The Influence of Biodegradable Microcapsule Formulations on the Controlled Release of a Protein," <i>J. of Controlled Release</i> 30:201-211 (1994).

EXAMINER	DATE CONSIDERED
----------	-----------------